

The future of NHS patient safety investigation

March 2018

We support providers to give patients safe, high quality, compassionate care within local health systems that are financially sustainable.

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1. Introduction

The NHS conducts patient safety investigations after things go wrong in patient care to learn from these events and to inform changes to prevent them happening again.

Compelling evidence from patients, families, carers and staff has revealed weaknesses in the way NHS organisations investigate, communicate and learn when things go wrong. This evidence is the cornerstone of many national reports and reviews (including reports by the Public Administration Select Committee in March 2015 [1], the government's response in July 2015 [2], the Parliamentary and Health Service Ombudsman's report [3] in December 2015 and the Care Quality Commission's (CQC) *Learning, candour and accountability* [4] in December 2016), and CQC cites these issues as one of its biggest concerns [5].

Those who have had a poor experience of NHS patient safety investigations have told us this can have a lasting social and physiological impact for patients, families, carers and staff alike. This has fuelled recent efforts to improve investigation practice to better support those affected by incidents and to prevent repetition of harm.

The establishment of the Healthcare Safety Investigation Branch (HSIB) in April 2017 is a significant step forwards and demonstrates the commitment to professionalising and improving how the NHS investigates incidents for the purpose of learning. HSIB will support improved practice across the NHS by undertaking exemplar investigations (and thereby demonstrating what good looks like) and supporting skill development [6]. But HSIB cannot investigate all the incidents requiring investigation in the NHS, and a continued focus on improving NHS patient safety investigation to support learning remains essential.

“The most toxic, damaging, compounding, devastating thing that happens is they drip feed you information, they give you a tiny closed off answer. Letters are sent Friday so they arrive Saturday morning, you've nowhere to go, nothing to do with it. Every single time a piece of information came through it raised another question, and another question, and another question.”

From CQC interview of a family member, *Learning, candour and accountability* (CQC 2016, p16)

2. The systems approach to safety

Decades of learning in healthcare and other industries has shown that individuals are rarely to blame when things go wrong. It is not true that if people simply try hard enough they will not make errors, or that punishment when they make errors leads to them making fewer of them. The safest organisations and industries recognise that people make mistakes and that the best approach to ensuring safety is to create systems, processes, practices, environments and equipment that support people to do their jobs as safely as possible. This systems approach to safety recognises that incidents are linked to the system in which individuals are working. Looking at what is wrong in the system helps organisations identify and address the root cause of a particular incident and therefore prevent it from happening again [7].

The systems approach to safety does not remove accountability. Our actions in healthcare must be explained and responsibility accepted. Along with increased public awareness of patient safety issues, expectation around accountability has been raised. Accountability for patient safety means being open with patients, families and carers about incidents, particularly those that result in harm, as described in the Duty of Candour [8], and explaining what happened. It also means explaining the scope and purpose of any investigation that may follow an incident, and how those affected can be involved.

Safety investigations are a means to achieving learning by systematically analysing what happened, how it happened and why, to identify effective and sustainable actions that can prevent the same thing happening again. Although boards of organisations are accountable for ensuring the above, a safety investigation is not conducted to hold any individual or organisation to account for the incident occurring. Where necessary, there are other processes for that, including criminal proceedings, disciplinary procedures, employment law and systems of service and professional regulation, such as those of CQC, the Nursing and Midwifery Council, the Health and Care Professions Council and the General Medical Council [9]. The findings from a safety investigation can be considered as part of the evidence gathered in other investigations (for example, the coroner's investigation), but the purpose (and terms of reference) of a safety investigation must not be confused or compromised by trying to meet different and competing needs (see Section 4.2).

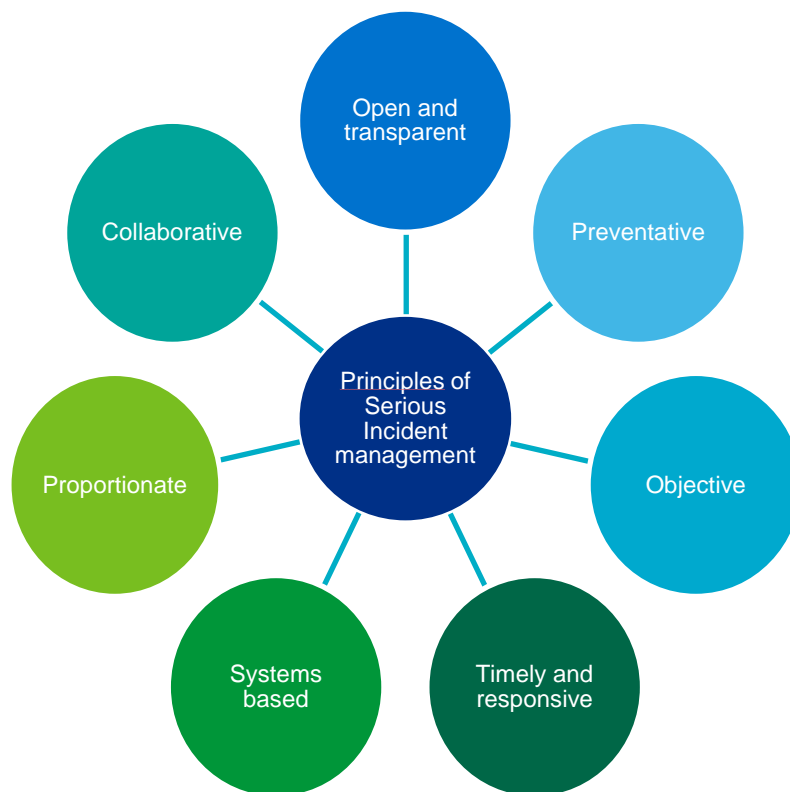
3. Building on the NHS Serious Incident framework

The current Serious Incident framework [9] published in 2015 sets expectations for when and how the NHS should conduct a safety investigation. It describes how to:

- identify and report Serious Incidents
- set up an investigation team
- involve patients, families, carers and staff (as well as other stakeholders)
- appropriately scope and define the purpose of an investigation
- develop an action plan
- submit the report to commissioners.

The framework also sets out seven principles that should underpin good safety investigation practice (see Figure 1).

Figure 1: Principles to support good investigation practice



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Many reports and reviews highlight that NHS organisations struggle to routinely underpin their investigations with these principles: investigations do not always appropriately involve and support patients, families, carers and staff; many are undertaken by staff without the necessary time and expertise; some focus too narrowly on care in specific settings and do not consider the care a patient received from several different organisations; too often they do not follow a systems-based methodology; and too many make weak recommendations that do not effectively address problems in care [4, 5, 10].

Figure 2 below summarises the main phases of current investigation practice and the most significant problems associated with each. It also identifies the underlying factors that may be contributing to these problems. Section 4 groups these factors under five common themes and discusses each in turn to elicit ideas for change.

We would like your input in revising the Serious Incident framework (2015). We want this framework to guide the system to respond more appropriately and effectively when things go wrong.

Clearly, revising the current framework cannot resolve all the issues facing patient safety investigation, but it can provide a foundation for good practice and for a broader programme of work to improve the quality of NHS patient safety investigation.

Please read this document and watch the recorded presentations on our [engagement website](#).¹

We invite your responses to particular questions. These are included in this document for completeness and context, but you need to submit your views to us by completing the [online survey](#).²

Our analysis of the factors that contribute to poor quality investigation is based on published reports and our recent work with NHS organisations to support investigation improvement. You may have additional insight or analysis as to why investigation is poor – please base your comments on your own knowledge as well as the information given here.

You can choose to complete the whole survey or only those sections of interest to you, but do review all sections of this discussion document first to provide relevant

¹ <https://improvement.nhs.uk/resources/future-of-patient-safety-investigation>

² <https://www.surveymonkey.co.uk/r/future-of-patient-safety-investigation>

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background. Problems and issues are often interlinked so it is useful to think about how to solve one problem with an awareness and understanding of the others.

NHS Improvement has not made any decisions about how to update the Serious Incident framework. We suggest changes for you to comment on but are interested in hearing all your ideas or insights.

An easy read version of this document and a survey will be made available on our [engagement website](#).³

³ <https://improvement.nhs.uk/resources/future-of-patient-safety-investigation>

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Figure 2: Summary of common problems associated with investigation in the NHS and the key contributory factors



4. Key factors contributing to poor investigation

4.1. Defensive cultures and lack of trust

The Serious Incident framework (2015) states that “the needs of those affected by Serious Incidents should be the primary concern” [9]. It also describes how patients, families (including those bereaved by mental health homicide), carers and staff should be involved and supported throughout the investigation process. Not only is it right to involve them, it is also essential for learning and future improvement as they are often the people who have the most comprehensive picture of what happened during their or their relative’s care.

Although most organisations acknowledge this, too frequently patients, families and carers describe a poor experience where they are not informed or involved and do not have an opportunity to have their questions heard and answered. Too often, NHS organisations do not share and engage with people openly [4, 5]. Whether this culture is deliberate or the inadvertent consequence of poor systems or fear about sharing information, it results in people losing trust in NHS organisations. As suspicion and mistrust develop, people seek answers by other means, often requesting an independent investigation or pursuing litigation.

The staff involved in Serious Incidents can also face a defensive approach from their employer. They are not always kept informed or involved in the investigation process and are sometimes dismissed from work or informally suspended pending investigation. They do not always receive the support they need. Indeed, if a report does mention the support staff received, this is typically a generic statement repeated from other reports [5].

“Despite pockets of best practice... incident investigation ... falls far short of what patients, their families, clinicians and NHS staff are entitled to expect. A culture of defensiveness and blame, rather than a positive culture of accountability, pervades much of the NHS.”

Investigating clinical incidents in the NHS, Sixth Report of Session 2014–15 (Public Administration Select Committee 2015, p54)

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Failure to support and involve staff allows a 'blame culture' to develop. This is reinforced when investigation reports infer that error is the fault of individuals by recommending periods of self-reflection or retraining to prevent incidents recurring. Although this may not be intentional, blame is directed at the individual(s) involved.

Your feedback/suggestions

4. How could the Serious Incident framework be revised to reduce defensiveness and increase openness so that patients, families, carers and staff are more effectively involved and supported? Please let us know your ideas.

5. How effective do you think each of the following approaches would be in promoting open and supportive involvement of patients, families and carers?

- A. Providing patients/families/carers with clear standardised information explaining how they can expect to be involved. This will mean they can more easily judge if an organisation is meeting these requirements and if it is not, raise this with the organisation (with support from their key point of contact; organisations are currently required to provide this contact).
- B. Requiring organisations to establish a process for gathering timely feedback from patients/families/carers about the investigation process. Concerns can be more easily addressed and reliance on the formal complaints process as a means of addressing potential problems reduced.
- C. Asking patients/families/carers to complete a standard feedback survey on receipt of the final draft investigation report that asks whether their investigations were met. This could help those responsible for overseeing investigations determine if a report can be signed off as complete.

6. How effective do you think each of the following approaches would be in promoting more open and supportive involvement of staff?

- A. Requiring organisations to have dedicated and trained support staff who listen to and advise staff on their worries and concerns following incidents.
- B. Requiring a formal assessment to be completed to determine whether an individual intended harm or neglect, acted with unmitigated recklessness, or has performance, conduct or health issues, before the employer takes any action against a staff member.
- C. Requiring those making judgements about the need for individual action to demonstrate up-to-date training and understanding of just accountability.

4.2. Inappropriate use of the Serious Incident process

Safety performance

The *National framework for reporting and learning from Serious Incidents requiring investigation*, published by the National Patient Safety Agency (NPSA) in 2010, was the first national guidance to set expectations for the reporting and investigation of Serious Incidents across the NHS. It attempted to bring consistency to practices across the NHS and provided examples of incident types that should be reported and investigated as Serious Incidents. Since this framework was replaced in 2015, the NHS has been encouraged to move away from using lists of specific incident types because these create a disproportionate focus on some incidents at the cost of others.

The reliance on lists has been driven in part by the belief that Serious Incident data can provide information and assurance about safety performance and improvement. When systems become aware of a new risk or want assurance about potentially high profile risks, the tendency is to mandate the reporting of those incidents as 'Serious Incidents' and to use that information to track performance. This approach is also used in response to perceived concerns about consistency of

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reporting, and a desire to ensure that organisations report all the incidents that they 'should' report.

But evidence shows that when incident reporting information is used for performance monitoring, people become concerned about being held to account for factors outside their control. Disputes between providers and commissioners can also arise because there is disagreement about the need to continuously invest resource in the investigation of incidents of a similar type. Multiple and varying definitions of 'preventable', 'avoidable', 'expected', 'unexpected', 'natural' or 'unnatural' have been introduced to try to rationalise and justify when incidents should be reported and investigated as Serious Incidents [4, 5].

The use of Serious Incident reporting and investigation for performance management can undermine learning and improvement in several ways, including:

- Incidents can be inappropriately defined as 'unavoidable' or 'expected' in advance of a careful review comparing the care provided with the care that would have been expected, given our understanding of acceptable clinical practice at the time and the wider circumstances within which the incident occurred. This can be a particular problem where the type of incident is currently difficult to prevent, where 'expected' complications arise or where a patient is receiving end-of-life care and problems are considered inevitable. By not considering if/where there were gaps in care, risks are left unmitigated and other patients are likely to be similarly harmed.
- There can be a reluctance to report incidents that are the result of problems in care across several settings. This links to a fear that organisations may be held to account for identifying and resolving issues beyond their sole control. Significant opportunities for learning and development from cross-system investigations, if carried out effectively, are lost.
- Investigations can be completed to satisfy a process, not to improve patient care. Currently, some investigations are being mandated regardless of circumstances; time is spent investigating very similar incidents which fail to generate new learning. This overloads the system and can result in: investigation fatigue (which can lead to recommendations being copied from previous reports); fragmented action planning and monitoring; and diluted improvement efforts. CQC's review of investigation reports supports the view that some incidents are being inappropriately treated and investigated as Serious Incidents [5]. One third of the reports examined by

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CQC showed no clear evidence that the criteria for Serious Incident reporting were met and in some cases, where numerous individual investigations were conducted for a particular incident type, CQC believed a multi-incident investigation may have been more effective [5].

In addition, evidence from other research suggests that more could be learnt about what went wrong (and how this can be avoided) by robustly investigating a selection of similar incidents, rather than superficially investigating certain incidents every time they occur [10–12]. A pilot conducted by the Patient Safety team⁴ found that high quality investigation of a selection of incidents of a very similar type (selected using risk management principles) does identify common systemic contributory factors. If these factors are addressed, the likelihood of the problems in care that lead to all incidents of a similar type could be significantly reduced [10–12].

“In-depth analysis of a small number of incidents will bring greater dividends than a cursory examination of a large number.”

Vincent C, Adams S. A protocol for the analysis of clinical incidents (1999, p3)
www.patientsafety.ucl.ac.uk/CRU-ALARMprotocol.pdf

Since the NHS is unlikely to be able to substantially increase its investment in safety investigation and because there is evidence (as described above) that current resource could be used more effectively, we need to consider how the system can improve the quality and efficacy of investigation and how the recommendations from investigations can be implemented to support more effective improvement activity.

We would like to consider whether resources could be used more effectively by being more selective; that is, prioritising incidents that require full investigation, investigating them to a high standard and implementing the actions informed by this to prevent future patient harm. At the same time we need to consider how organisations can respond appropriately to other incidents that are not prioritised for full investigation (for example, because ongoing improvement work is already delivering demonstrable improvement/reduction of risk).

⁴ This involved investigation experts conducting high quality investigations into incidents of a similar type to determine if this harnessed the full potential of investigation to inform learning and measurable patient safety improvement.

Inappropriate extension of scope and purpose

Over time, the Serious Incident process appears to have led to a reliance on the safety investigation process as a means of responding to all types of issues, including those associated with litigation, a coroner's inquest or professional competency/fitness to practice.

As a result, safety investigations often make inappropriate judgements about predictability, preventability and/or cause of death, rather than focusing on the problems in care and how and why these occurred. It is important to note that a safety investigation **can** inform other important processes. For example, a coroner may include the findings of a Serious Incident investigation as part of the evidence in their own report, but the terms of reference of the safety investigation and the coroner's inquest must not be confused – that is, safety investigations should not seek to determine the cause of death.

Similarly, the process of conducting a Serious Incident investigation and the findings from an investigation must of course be used to support a conversation with those affected by an incident, as far as possible meeting their need to understand what happened and why. However, in some cases those affected may want an outcome that is not within the remit of a safety investigation. For example, they may want to know who is accountable for what happened and whether those persons will remain in post. While the current Serious Incident framework states these concerns must be managed separately from the safety investigation, there is evidence that this separation is not always maintained. Of course, occasionally a safety investigation may reveal evidence that an individual's actions may have been unacceptable; if it does, these issues need to be referred to the individual's employer and potentially their professional regulator. **The safety investigation itself is conducted for the purposes of learning only.**

“It is very difficult for a single RCA [root cause analysis] investigation report to satisfy the needs of all stakeholders, that is the trust (so that it learns), the family, commissioners, coroner, CQC, other involved organisations, and so on.”

Provider information request submitted by a Mental Health Trust, CQC (2016).
Learning, candour and accountability
(CQC 2016, p43)

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There can also be pressure to declare a Serious Incident, as not doing so might lead to perceptions that the incident is not being treated seriously, or that specific questions from patients, families, carers and staff cannot be answered. However, information from the incident report and early review of what happened often hold the answers to questions. A full investigation is not always necessary; potentially there needs to be less reliance on the safety investigation process and prioritisation of incidents that do warrant a full investigation, based on risk and the potential for learning and improvement.

Your feedback/suggestions

8. How could the Serious Incident framework best support more effective use of investigation resources? Please tell us your ideas.

9. How effective do you think each of the following approaches would be in promoting better use of existing investigative resources?

- A. Continuing to discourage the use of prescriptive Serious Incident lists as a tool for reporting.
- B. Setting minimum resource requirements for an investigation team.
- C. Setting a nationally agreed minimum number of investigations for each organisation (based on the size of the organisation) so that each organisation can plan how it achieves this number with the appropriate resources to deliver good quality outputs.
- D. Requiring organisations annually to develop an investigation strategy that identifies and describes which incidents will be investigated and how their investigation will be resourced.
- E. Stating that incidents do not always have to be investigated if an ongoing improvement programme is delivering measurable improvement/reduction of risk.

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- F. Providing decision aids and record-keeping templates that help determine which incidents should be fully investigated.
- G. Providing information on other processes for managing incidents that may be appropriate for certain types of concerns/issues raised.

4.3. Misaligned oversight and assurance processes

The Serious Incident framework states that the provider organisation is responsible for the management of the Serious Incident investigation. The commissioner (NHS England and/or clinical commissioning groups – CCGs) of the organisation (or more specifically the service) in which the incident occurred is responsible for quality assuring the investigation report and agreeing closure once an investigation is deemed complete.

NHS England, CQC and NHS Improvement also have an interest in the overall effectiveness of systems for learning, and often request information on specific cases as well as broader performance data for Serious Incident investigations.

While these processes seek to maintain and improve the quality of Serious Incident management, the evidence of the various reports showing the quality of investigation is generally not good enough suggests that a more considered approach to oversight and assurance may be needed. One issue is that the performance metrics used are often relatively simple and process focused. For example, the number of Serious Incidents reported and compliance with the 60-day deadline for report completion do not provide information on the quality of

“Some types of measurement introduce perverse incentives that can lead to box ticking or other unwanted behaviour. Instead, we need a more holistic approach ... We believe that the primary question posed by regulators should be not ‘Show us how you are complying with our standards’, but ‘Demonstrate your organisation's approach to safety measurement and monitoring.’”

Vincent et al. Safety measurement and monitoring in healthcare: a framework to guide clinical teams and healthcare organisations in maintaining safety. *BMJ Qual Saf* 2014;**23**:670–677.

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investigation when considered in isolation. Focusing on these metrics can also drive unintended consequences. For example, patients, families and key staff members may not be involved in the investigation process because this takes time and could result in a 'breach' of the 60-day deadline.

Following the oversight and assurance processes can therefore, paradoxically, have a detrimental effect on the quality of investigations.

Another problem with the current approach to Serious Incident oversight and assurance is that it does not encourage working across organisational boundaries. Each reported Serious Incident is typically attributed to an individual organisation and the prescribed timeframes for report completion make it difficult to identify and build relationships with other teams. Even where different sites/organisations recognise the need to investigate the same incident, they tend to conduct separate investigations rather than collaborating; this can miss gaps across the system.

Your feedback/suggestions

11. What changes could be made to the assurance processes to better foster an environment for learning and improvement? Please tell us your ideas.

12. How effective do you think each of the following approaches would be in developing an environment for learning and improvement?

- A. Providing clearer descriptions of roles and responsibilities at each level of the system.
- B. Requiring a designated trained person in provider and commissioning organisations to oversee processes associated with Serious Incident management.
- C. Setting minimum training requirements for board members and commissioners signing off investigation reports (covering behaviours as well as process to support learning and improvement).

- D. Introducing a standardised quality assurance tool to support investigation sign off and closure.
- E. Requiring increased involvement of patient and family representatives in the sign off process.

14. What changes could be made to the framework to identify and facilitate cross-system investigations? Please tell us your ideas.

15. How effective do you think each of the following approaches would be in helping organisations to identify and conduct cross-system investigations?

- A. Requiring a cross-system investigation to be considered each time an investigation is initiated and, if it is not considered appropriate, the recording of why.
- B. Having a designated trained lead in all sustainability and transformation partnerships who can work with all relevant organisations when a cross-system investigation is necessary.
- C. Continuing to discourage the use of Serious Incident data for performance management.
- D. Mandating through contracts/future regulation the need to contribute to cross-system investigations as required.
- E. Rewarding those who initiate and/or engage in cross-system investigation.

4.4. Lack of time and expertise

Investigation is complex and requires expert skill and knowledge. As well as reconstructing a scenario, investigators need to source and organise evidence from experts and those involved, such as patients, families, carers and staff. They then need to analyse this information to understand how and why problems occurred [13]. An understanding of human factors and improvement science is essential for clarifying what problems occurred, determining why they may have occurred and recommending what should be done to prevent their recurrence [13, 14].

Relationships with those who might be experiencing one of the most traumatic times in their lives also need to be established and maintained. Despite these challenges, investigators are often clinicians or managers who have had limited training in the science of investigation. They may not have had an opportunity to shadow or seek support from experienced investigators before they are asked to lead their own investigation for the first time.

“The person who did the investigation did not have any experience or qualification. The main people who were in charge of my son’s care were not interviewed...”

CQC interview, *Learning, candour and accountability* (CQC 2016, p19)

Investigators are also given limited time to undertake the investigation, which can mean they often have to work additional and unpaid hours to do so. The national recommended timeframe for completion of an investigation and submission of the report to the commissioner is 60 working days. However, internal approval of the investigation report before submission can take time because relevant committees will need to sign it off. In some cases, the most time-consuming parts of the investigation process (such as interviewing those affected, including patients, families, carers and staff) are omitted to meet demand and to comply with the strict timeframes driving organisations’ internal processes.

Problems also exist at other levels of the system. As previously described, commissioners and oversight bodies have a role in approving and overseeing Serious Incident investigations. However, they too may not have the necessary time and/or expertise to manage their responsibilities as currently prescribed in the Serious Incident framework. This can exacerbate the issues associated with misaligned oversight processes (described above) which focus too heavily on the

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simplistic process measures that are used inappropriately to monitor safety performance.

Your feedback/suggestions

17. How could the Serious Incident framework best ensure the necessary time and expertise is devoted to investigation? Please tell us your ideas.

18. How effective do you think each of the following approaches would be in ensuring the necessary expertise is devoted to investigation?

Skills/capability

- A. Requiring each provider to have a flexible, trained team of investigators comprising staff employed by the organisation who combine investigation and management or clinical roles, but have dedicated and protected time for investigation duties. Additional clinical or managerial expertise should be sought as required on a case-by-case basis.
- B. Requiring each provider to have a dedicated team of trained lead investigators with no duties in that organisation other than investigation. Additional clinical or managerial expertise should be sought as required on a case-by-case basis.
- C. Requiring each provider to base the number of investigators it employs on its size and the number of investigations it expects to conduct each year, eg four whole time equivalent (WTE) lead investigators to conduct 20 investigations a year.
- D. Requiring each provider to have a trained head of investigation who selects, supports and oversees patient safety investigation management processes.
- E. Requiring a trained head of investigation oversight for commissioning organisations.

19. How effective do you think each of the following approaches would be in ensuring the necessary time is devoted to investigation?

Timeframes for reporting

- A. Removing the 60 working day timeframe and instead allowing the investigation team to set the timeframe for each investigation in consultation with the patient/family/carer (as is often the case in the complaints process).
- B. Keeping the set timeframe at 60 working days but reducing the number of investigations undertaken.
- C. Keeping the set timeframe at 60 working days but requiring organisations to rationalise their internal approval processes to allow more time for investigation before external submission.
- D. Recommending a 60 working day timeframe but allowing providers some leeway on meeting it and not managing performance against it.

4.5. Inconsistent use of evidence-based investigation methodology

The current Serious Incident framework endorses evidence-based tools and templates, and describes what an investigation must involve – commonly referred to as root cause analysis (RCA). However, CQC [5] found that only 8% of the investigation reports it reviewed showed evidence of a clearly structured methodology that identified the:

- key issues to be explored and analysed
- contributory factors and underlying system issues
- key causal factors that led to the incident.

One of the most common issues is disproportionate focus on some of the activities associated with the first two phases of the investigation process (that is, setting up

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the investigation and gathering information; see Appendix 1), and not enough focus on many of the essential activities required as part of the later phases (that is, the analysis of problems and identification of key contributory factors) [10].

Consequently, investigations often use relatively limited sources of information – such as clinical notes and written statements – to establish what happened. Based on this, they make inappropriate conclusions that typically concentrate on judgements about avoidability, preventability or predictability, which is not the purpose of a safety investigation (as described earlier).

In addition, and with reference to issues associated with time and pressures from the wider system, investigators are often asked to conduct RCAs to satisfy the needs of many stakeholders. This can lead to a conflict of purpose when issues such as liability, professional performance and cause of death are considered in the same report.

Therefore, while RCA is widely used and considered to be the national systems-based investigation method, it is often not understood or appropriately adopted in local investigations. The RCA method is sometimes cited as the cause of investigation flaws, but review of such published critiques [13] suggests problems with implementation rather than fundamental flaws in the RCA methodology.

HSIB is expected to support the spread of good practice in investigation and may recommend that new investigation methodologies are used across the NHS. But for now it is important to maximise the usefulness of the current approach.

As part of its development work, HSIB has created its own set of principles for its investigations. While the current Serious Incident framework does give seven principles of investigation (see Section 3), we are proposing to revise these to align them with HSIB's principles and to emphasise the importance of a strategic and an expert approach to local patient safety investigation. The proposed principles are given in Appendix 2 and we are interested in people's views on them.

Your feedback/suggestions

21. How could the Serious Incident framework support uptake of evidence-based investigation approaches? Please tell us your ideas.

22. How strongly do you agree that a mandated investigation report template and assurance checklist could help to standardise and improve evidence-based practice across the NHS?

24. A revised set of principles has been drafted for your consideration (see Appendix 2). Do you think these principles could support the implementation of good practice?

25. Do you think these principles are clear and comprehensive?

26. Is there anything you would add or change in the drafted principles? Please give us your ideas.

27. Do you think the name of the Serious Incident framework should be changed to reflect the step change in process and behaviour that may be required in some areas to embed good practice? If yes, can you suggest a name?

5. Next steps

The survey will remain open until **12 June 2018**. After this date all responses will be analysed to identify how the Serious Incident framework could be revised to improve the quality of NHS patient safety investigation and the action that follows to prevent the recurrence of harm.

The Serious Incident framework will be redrafted over the summer 2018. Further information will be made available on the NHS Improvement website and through our communication channels.

If you have problems accessing the survey please contact us at patientsafety.enquiries@nhs.net

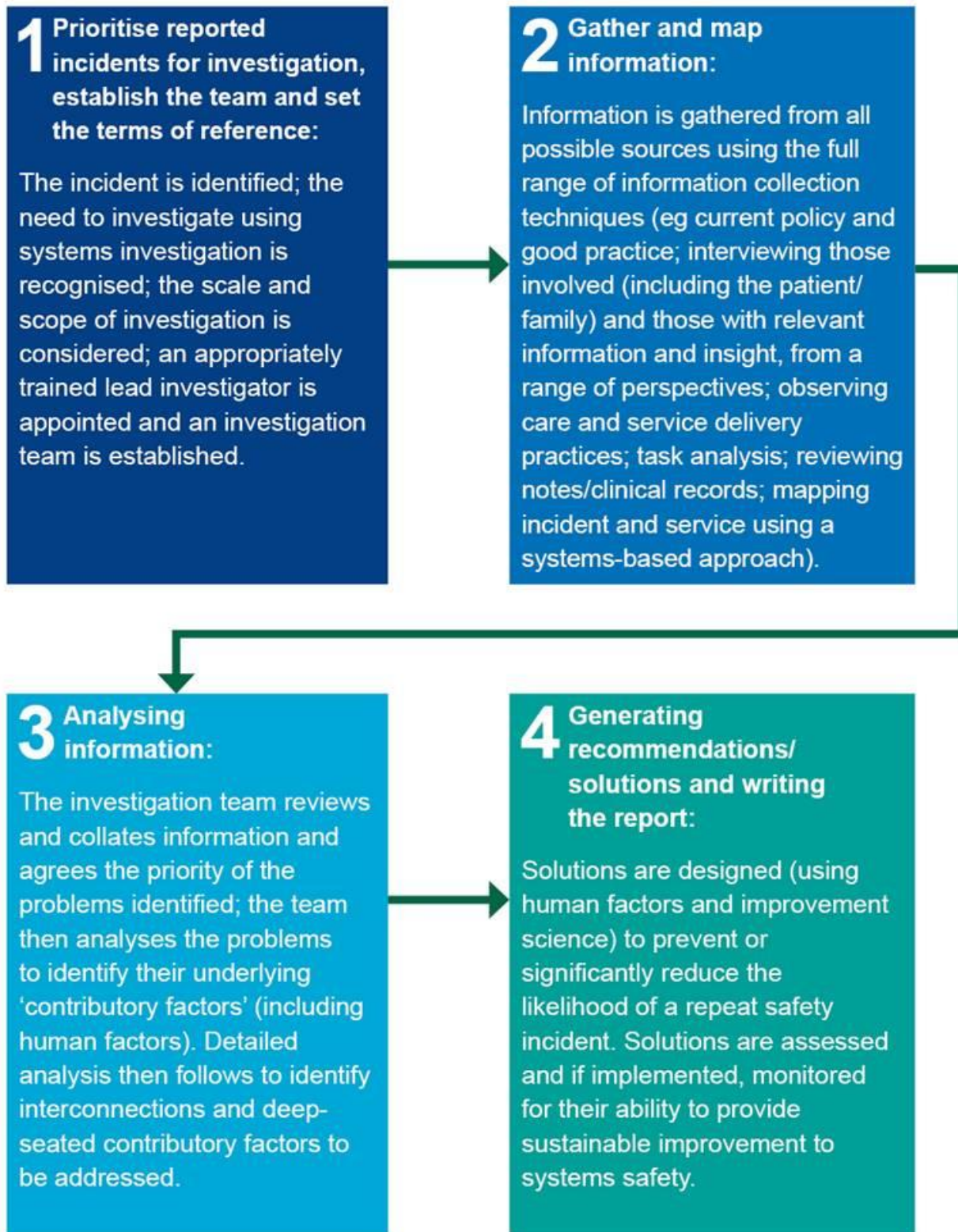
References

1. Public Administration Select Committee (2015) *Investigating clinical incidents in the NHS. Sixth Report of Session 2014–15*. Available online at: <https://publications.parliament.uk/pa/cm201415/cmselect/cmpublicadm/886/886.pdf>
2. Department of Health (2015). *Learning not blaming: response to 3 reports on patient safety*. Available online at: www.gov.uk/government/publications/learning-not-blaming-response-to-3-reports-on-patient-safety
3. Parliamentary and Health Service Ombudsman (2015). *A review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged*. Available online at: www.ombudsman.org.uk/publications/review-quality-nhs-complaints-investigations-where-serious-or-avoidable-harm-has
4. Care Quality Commission (2016). *Learning, candour and accountability*. Available online at: www.cqc.org.uk/sites/default/files/20161213-learning-candour-accountability-full-report.pdf
5. Care Quality Commission (2016) *Learning from harm: Briefing paper*. Available online at: www.cqc.org.uk/sites/default/files/20160608_learning_from_harm_briefing_paper.pdf
6. Healthcare Safety Investigation Branch (2018) *How we work*. www.hsib.org.uk/
7. National Patient Safety Agency (2004) *Seven steps to patient safety: full reference guidance*. Available online at: www.nrls.npsa.nhs.uk/resources/?entryid45=59787
8. Care Quality Commission (2015). *Regulation 20: Duty of Candour*. Available online at: www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf

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9. NHS England Patient Safety Domain (now NHS Improvement) (2015) *Serious Incident framework: Supporting learning to prevent recurrence*. Available online at: <https://improvement.nhs.uk/resources/serious-incident-framework/>
10. Forsyth DL (2018) *Fewer, better investigations, shifting the focus of patient safety investigation from quantity to quality*. In press.
11. Vincent C (2011) *The essentials of patient safety* (adapted from *Patient safety*, 2nd edition). Available online at: www.chfg.org/wp-content/uploads/2012/03/Vincent-Essentials-of-Patient-Safety-2012.pdf
12. Adams S, Vincent C. (1999). *A protocol for the investigation and analysis of clinical incidents*. Available online at: www.patientsafety.ucl.ac.uk/CRU-ALARMprotocol.pdf
13. Peerally MF, Carr S, Waring J, et al (2017) The problem with root cause analysis. *BMJ Qual Saf* 26:417–422.
14. Kellogg KM, Hettinger Z, Shah M, et al (2017) Our current approach to root cause analysis: is it contributing to our failure to improve patient safety? *BMJ Qual Saf* 26:381–387.

Appendix 1: Process overview for NHS patient safety investigation



Appendix 2: Proposed principles for the revised Serious Incident framework

Strategic	<p>Boards focus on quality of output, not quantity.</p> <p>Resources are invested to support quality outputs.</p> <p>Boards recognise the importance of findings.</p> <p>There is a culture of learning and continuous improvement.</p>
Preventative	<p>Investigations identify and act on deep-seated causal factors to prevent or measurably and sustainably reduce recurrence.</p> <p>They do not seek to determine preventability, predictability, liability, blame or cause of death.</p>
People focused	<p>Patients, families, carers and staff are active and supported participants.</p>
Expertly led	<p>Investigations must be led by trained investigators with the support of an appropriately resourced investigation team to ensure they are:</p> <ul style="list-style-type: none"> • open, honest and transparent • objective • planned • timely and responsive • systematic and systems-based • trustworthy, fair and just.
Collaborative	<p>Supports system-wide investigation (cross pathway/boundary issues)</p> <p>Enables information sharing and action across systems</p> <p>Facilitates collaboration during multiple investigations</p>

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